510(k) Summary F

F.1 Company

NOV 12 1996 K962792

Surgical Navigation Technologies, Inc. 530 Compton Boomfield, CO 80020 USA

Product Name F.2

LINAC Scalpel Treatment Planning System

F.3 Description

The LINAC Scalpel Treatment Planning System is a radiation treatment planning system composed of a high resolution UNIX graphics computer, a printer a digitizing graphics tablet, and radiation treatment planning application software.

Intended Use and Indications F.4

The LINAC Scalpel Treatment Planning System is intended as a aid in quickly and precisely planning the radiation treatment of small cranial lesions such as arteriovenous malformations, pituitary tumors, pinealomas, acoustic neuromas and malignant neoplasms.

Substantial Equivalence F.5

The LINAC Scalpel Treatment Planning System was claimed to be substantially equivalent to commercially available Radiation Treatment Planning Systems Information pertaining to these systems was provided in the submission.